

I. Rejections Under 35 U.S.C. §112, First Paragraph

Claims 1, 3, 5, 7, 13 – 15, 17, and 23 – 25 stand rejected under 35 U.S.C. §112, first paragraph, as lacking enablement. The Examiner asserts that the claims are enabled for KGF and plasminogen or plasmin, but not for all growth factors and proteases. The Examiner argues that it would be an undue burden on one of ordinary skill in the art to have to test “any and all proteases and growth factors” to determine which are operable under the current claims. The Examiner also asserts that the specification does not provide enough guidance to allow those of ordinary skill in the art to arrive at the claimed composition that produces the unexpected results.

Applicants respectfully disagree with the Examiner’s position and assert that the claims are enabled as written. In support of this argument, Applicants have submitted a declaration under 37 C.F.R. §1.132 from Dr. Yawei Ni, one of the inventors of the claimed subject matter. As stated in Dr. Ni’s declaration, anyone of ordinary skill in the art is fully capable of using the teachings of the specification to produce effective combinations of growth factors and proteases according to the claims.

In particular, a number of possible growth factors and proteases are given in the specification, at Page 23, lines 12 – 19, as well as in Example 10. These may be combined in any manner according to the claims. Although certain combinations could be ineffective for the purposes of the claims, this can be readily determined by carrying out the electrophoretic analysis and biological function tests that are described in Examples 1 – 5. The electrophoretic analysis shown in Examples 1 – 4 simply involves the use of gel electrophoresis to determine whether a growth factor protein band remains on the gel or whether the protein has been degraded by the protease enzyme. If there is no band, then the growth factor protein is not stable in that combination. The biological function test is typically a cell proliferation assay, as shown in Example 5. If the growth factor protein is degraded in a particular combination with a protease enzyme, then it will not be capable of stimulating cell division or proliferation in the assay. This simple test, which has been described extensively in the literature, will also inform a

person of skill in the art whether the combination is effective. Neither of these tests involves undue experimentation, as both are well within the ordinary skill level of those in the field.

Furthermore, by rejecting the claims for lacking enablement, the Examiner is improperly requiring that the claim language itself distinguish between operable or inoperable embodiments. It is not a function of the claims to specifically exclude either possible inoperative substances or ineffective reactant proportions. *See In re Dinh-Nguven and Stenhagen*, 492 F.2d 856, 858 – 59 (C.C.P.A. 1974). The only requirement is that the specification provide sufficient guidance to allow the person of ordinary skill in the art to practice the claimed invention. As discussed in the declaration, the specification is clearly adequate and those of skill in the art will have no trouble determining which combinations are effective. Requiring the claims to discriminate between all workable and non-workable embodiments is unreasonable and improper. To provide effective incentives, claims must adequately protect inventors. Demanding that an inventor limit his claims to what he has found will work or to any preferred materials in a process would not serve the constitutional purpose of promoting progress in the useful arts. *See In re Goffe*, 542 F.2d 564, 567 (C.C.P.A. 1976).

For these reasons, Claims 1, 3, 5, 7, 13 – 15, 17, and 23 – 25 are sufficiently enabled by the specification and are patentable.

II. Conclusion

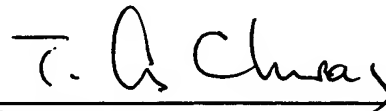
Applicants respectfully submit that, in light of the foregoing comments, Claims 1, 3, 5, 7, 13 – 15, 17, and 23 – 25 are in condition for allowance. A Notice of Allowance is therefore requested.

Attorney Docket No.:
CARR-0084 (103216.00252)

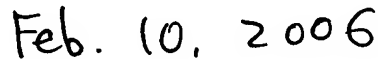
PATENT

If the Examiner has any other matters which pertain to this Application, the Examiner is encouraged to contact the undersigned to resolve these matters by Examiner's Amendment where possible.

Respectfully submitted,



T. Ling Chwang
Registration No. 33,590
JACKSON WALKER L.L.P.
2435 North Central Expressway, #600
Richardson, TX 75080
Tel: (972) 744-2919
Fax: (972) 744-2909



Date